NOV 1 3 2002 K022719

Section E- 510(k) Summary

Submitted by: Phil Reaston and MaryRose Cusimano PhD.
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Date Prepared: July 26, 2002
Contact: Dr. Cusimano
Product Trade Name: Physical Monitoring Registration Unit
Classification Name: PRMU, Surface EMG range of motion system Electromyography Diagnostic (890.1375)

List of Predicate Devices to which we claim substantial equivalence:

1. Combined Physiological Monitoring System (K002104)
2. Integrated Movement Analyzer (K944787)
3. Davicon Medic System (K914920)
4. Nuerocom EMG (K901732)
5. Nicolet Viking 2 (K8904950

Description of Physical Monitoring Registration Unit, Device

The Physical Monitoring Registration Unit, (PMRU) combines up to 48 channels allowing for a minimum of 18 channels of refined surface EMG to monitor any muscle group in the body. This is also beneficial in monitoring the cardiac muscle. This system also features lead status circuitry to integrate correct placement of all EMG electrodes. The additional channels monitor functional capacity sensors range of motion, the J-Mar grip and pinch strength measurement devices.

Intended Use of Physical Monitoring Registration Unit Device

To provide non-invasive muscle testing integrating with range of motion, functional capacity of lifting, pulling, pushing, pinching and gripping. To pinpoint muscle activity during movement objectively isolating abnormal movements with abnormal muscle patterns. To establish relative functioning of muscle in any specific anomaly that may occur due to muscle damage, muscle fatigue, hypertonicity or stress. To pinpoint referred pain pattern associated with cervical, thoracic, lumbosacral upper and lower extremities, and refer pain sources. To evaluate a baseline muscle activity for pre-employment screening, sport medicine. To look at chronic vs. acute muscle function and range of motion to ascertain good effort with FCE, range of motion, and gripping, and pinch. To ascertain the ischemic activity of muscles. To ascertain chronic damage to muscles. To monitor the frequency range for cardiac muscle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2002

MaryRose Cusimano, Ph.D
5367 NW 90th Avenue
Sunrise, Florida 33319

Re: K022719
Trade/Device Name: Physical Monitoring Registration Unit
Regulation Number: 890.1375
Regulation Name: Diagnostic Electromyograph
Regulation Class: II
Product Code: IKN
Dated: July 26, 2002
Received: August 15, 2002

Dear Dr. Cusimano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section D- Indications for Use

Surface electromyography with range of motion, functional capacity assessment grip and pinch strength.

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022719